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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,280	06/20/2006	Simon Joel	133088.00501(P34922US)	3592
35151	7590	10/04/2007	EXAMINER	
Pepper Hamilton LLP			CARR, DEBORAH D	
500 Grant Street			ART UNIT	
One Mellon Bank Center, 50th Floor			PAPER NUMBER	
Pittsburgh, PA 15219-2502			1621	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/535,280	JOEL ET AL.
	Examiner Deborah D. Carr	Art Unit 1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 41-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 41-63 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date: _____.                                     |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/05</u> .   | 6) <input type="checkbox"/> Other: _____.                         |

**DETAILED ACTION*****Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless—

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 57 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ma et al. or Montedison (GB 2,101,600) or Cass et al. or Gourdie et al. or Flemming et al. or Cai et al. or Barrett et al. or Bunce et al. or Lafon (US Pat. 4,013, 776) or Kalgutkar et al. or Cowart et al. or Dannhardt et al.

Thus, documents cited supra each describe at least one compound falling within the scope of claim 57 and Kalgutkar et al. or Cowart et al. or Dannhardt et al. also indicate that the relevant compounds therein have pharmaceutical use.

In particular, Cass et al. describes methyl 6-(phenylsulphinyl) hexa-2E, 4E-dienoate (compound 16) which is a compound of claim 57 in which R1 is phenyl, Y is 1 oxygen atom, n is 1, the dotted line represents a double bond, R2 and R3 are hydrogen atoms, Q is a CH=CH group and X is a methoxycarbonyl group. Indeed, this compound is the same compound as example 8a of the present application.

Gourdie et al. describes methyl 6-[(4-aminophenyl) thio] hexanoate (compound 25c) which is a compound of claim 57 in which R1 is 4-aminophenyl, Y is "0 oxygen atoms", n is

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1, the dotted line represents a single bond, R2 and R3 are hydrogen atoms, Q is a CH<sub>2</sub>-CH<sub>2</sub> group and X is a methoxycarbonyl group. Indeed, this compound is the same as the compound of example 28d of the present application.

*Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 58-63 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting histone deacetylase, does not reasonably provide enablement for the instant compounds in the treatment of cancer, cardiac hypertrophy, a hematological disorder, an auto-immune disease, a neurological condition, a genetic-related metabolic disorder, a peroxisome biogenesis disorder, adrenoleukodystrophy, stimulating hematopoietic cells ex vivo, ameliorating protozoal parasitic infection, accelerating wound healing, protecting hair follicles, specifically cancers selected from the group consisting of breast cancer, colon cancer, colorectal cancer, esophageal cancer, glioma, lung small and non- small cell cancers, leukemia neuroblastoma, prostate cancer, thoracic cancer, melanoma, ovarian cancer, cervical cancer and renal cancer.

The specification does not enable any person skilled in the art to which it pertains, or

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with which it is most nearly connected, to use the invention commensurate in scope with these claims.

At present, only 6-benzenesulfonyl-hexa-2, 4-dienoic acid hydroxamide and 6-(4-chloro-benzenesulfinyl)-hexa-2, 4- dienoic acid hydroxamide has been shown to exhibit HDAC inhibitory activity (pages 65-68). Since it is known in the pharmaceutical field that e.g. small structural changes may severely influence the efficacy, it is doubtful that this result credibly reflects the desired efficacy of all derivatives as claimed. Thus, at present it is considered that the problem posed is not solved over the whole area as claimed.

In support of scope of enablement, the applicant is therefore kindly requested to provide further data and/or convincing evidence or to delimit the scope of the claims accordingly.

While working examples are not required, where applicant defines the invention in Markush form, each member of the Markush group should be specifically contemplated in the specification and the specification should at least contain a generic teaching of how to prepare the compounds whose preparation is not specifically disclosed.

Enablement for a single compound cannot provide enablement for the breadth of claims sought in arts, which are unpredictable. Ex parte Hitzeman, 9 USPQ2d 1821 (BPAI 1987) (a single embodiment may provide broad enablement in cases involving predictable factors, but more is required in cases involving unpredictable factors, such as chemical or

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physiological activity); In re Shokal, 242 F.2d 771, 113 U.S.P.Q. 283, 285 (C.C.P.A. 1957) (a single species is seldom, if ever, sufficient to support a generic claim); In re Langer, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974) (proof of utility for the preferred species does not necessarily establish the utility of the remaining members of the genus); Ex parte Lanham, 135 USPQ 106 (POBA 1961) (biological activity of chemicals is notoriously unpredictable).

Applicants have shown broadly HDAC inhibitory activity can be induced using the specific compounds 6-benzenesulfonyl-hexa-2, 4-dienoic acid hydroxamide and 6-(4-chloro-benzenesulfinyl)-hexa-2, 4- dienoic acid hydroxamide. It should also be noted that while applicants have shown these compounds broadly exhibit HDAC inhibitory activity, there is no indication this activity extrapolates to the treatment of the ailments listed supra. One might gleam that ailments caused by the presence of HDAC should be treated by the inhibition of HDAC but to encompass all of the ailments listed supra not caused by HDAC would be difficult to accept in conventional arenas.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 41-63 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 41 is rendered indefinite for the following reason: R4 is not defined in the body of the claim. Claim 56 contains compounds that read on moieties not disclosed in the body of claims 41-44.

7. Claims 51-55 recite the limitation "R1" in line 1. There is insufficient antecedent basis for this limitation in the claim.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah D. Carr whose telephone number is 571-272-0637. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or

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access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or

571-272-1000.



**DEBORAH D. CARR  
PRIMARY EXAMINER**

ddc